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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,723	10/11/2001	Gary Nackman	601-1-101N	8417
23565	7590	06/28/2004	EXAMINER	
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			SRIVASTAVA, KAILASH C	
			ART UNIT	PAPER NUMBER

1651

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/975,723

**Applicant(s)**

NACKMAN ET AL.

**Examiner**

Dr. Kailash C. Srivastava

**Art Unit**

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                                |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____                                                             | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The assigned Examiner to your application in the USPTO is Dr. Kailash C. Srivastava. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1651.

2. Applicants' amendment filed January 29, 2002 is acknowledged and entered.

### ***Claims Status***

3. Applicants to note that Claims 1-33 have been correctly renumbered as 1-34 as provided by 37 CFR §1.141.

4. Claims 1-34 are pending.

### ***Election/Restriction***

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I – Claims 1-15 and 23-27 drawn to a method to populate a solid surface with human cells via enhancing cell to cell cohesion, classified under Class 435, subclass 395 for example.

Group II – Claims 16-20 drawn to a composition, i.e., a cell-coated solid surface, classified under Class 435, subclass 325 for example.

Group III – Claims 21-22 drawn to another composition, i.e., cell population, classified under Class 435, subclass 366 for example.

Group IV – Claims 28-33 drawn to a method to populate a solid surface with non-human cells, classified under Class 435, subclass 363 for example.

Group V – Claim 34 drawn to a method to determine phosphorylation, classified under Class 435, subclass 375 for example.

6. The inventions are distinct, each from the other because of the following reasons:

Inventions in Group I is related to inventions in Groups II-III as a process and products made by the process. The inventions are distinct if either or both of the following can be shown: (1) that the

process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the method to cultivate cells on a solid support can also be applied to prepare culture/ population of any cell type. The compositions (i.e., products, e.g., cell coated solid support or cell population) claimed in Inventions of Groups II and III may also be prepared by rehydrating freeze dried preparations in a culture medium.

Invention in Group I is unrelated to invention in Group IV because they are directed to inventions that are not connected in design, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, steps, compositions and/or they have different effects. One would not have to practice the various inventions at the same time to practice just one invention alone (MPEP § 806.04, MPEP § 808.01). In the instant case for e.g., invention disclosed in claims encompassing invention in Group I is directed to a method to cultivate human cells, whereas invention in Group IV is directed to a method for non-human cells.

Invention in Group I is related to invention in Group V as a process of making a product and applying the product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed method to cultivate cells may also be applied to cultivate any cell (e.g., microbial cell). Likewise, the claimed method of invention V encompassing Claim 34 is applicable to evaluate any physiological/ metabolic function (e.g., ion transport) in a human cell.

Inventions in Groups II-III are related to each other as combination/ sub-combination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the sub-combination as claimed for patentability, and (2) that the sub-combination has utility by itself or in other combinations [MPEP § 806.05(c)]. In the instant case, the combination (the cell population in invention of Group III) does not require the particulars of the sub-combination as claimed for patentability because the combination, by itself would be patentable even if the sub-combination (a cell population) was known and non-obvious, assuming that the prior art does not teach or suggest the presence of the additional ingredients recited in the combination claims. The sub-combination has utility of its own because it will be applicable for any application (e.g., to make a product) rather than the one claimed instantly.

Inventions in Groups II-III are unrelated to invention in Group IV because they are directed to inventions that are not connected in design, operation and/or effect. These inventions are independent

since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, steps, compositions and/or they have different effects. One would not have to practice the various inventions at the same time to practice just one invention alone (MPEP § 806.04, MPEP § 808.01). In the instant case for e.g., invention disclosed in claims encompassing invention in Group III encompassing Claims 21-22 is drawn to a composition comprising human cells, whereas invention in Group IV is directed to a method to cultivate non-human cells.

Inventions in Groups II and III are related to invention in Group V as product and use thereof. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product [MPEP § 806.05(h)]. In the instant case, the human cells could be cultivated in a variety of ways on different types of support that are well known in the art (See, for e.g., USGPB20040106545, Page 22, Paragraph 0285). Alternatively, the product may be applicable to evaluate any physiological function of a cell (e.g., production of an enzyme).

Inventions in Groups IV and V are unrelated to each other because they are directed to inventions that are not connected in design, operation and/or effect. These inventions are independent since they are not disclosed as capable of use together. They have different modes of operation, they have different functions, steps, compositions and/or they have different effects. One would not have to practice the various inventions at the same time to practice just one invention alone (MPEP § 806.04, MPEP § 808.01). In the instant case for e.g., invention disclosed in claims encompassing invention in Group V is directed to cultivated human cells, whereas invention in Group IV is directed to a method for non-human cells.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each one of the above inventions is not coextensive particularly with regard to the literature search. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification (class/subclass), a requirement for independent search as explained above and their recognized diverse subject matter, restriction for examination

purposes as indicated is proper.

7. Applicants are advised that a reply to this requirement must include an identification of an invention elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.


Upon the allowance of a generic claim, applicants will be entitled to consideration of additional claims which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR §1.141. Currently, Claims 1, 16, 18, 21-23, 28 and 29 are generic claims. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


8. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR §1.48(b). Any amendment of inventorship must be accompanied by a petition under 37 CFR §1.48(b) and by the fee required under 37 CFR §1.17(I).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571)-271-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (571)-271-0926 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(571)-271-0923

  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200

June 21, 2004